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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/717,158

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Ling Yuk Cheung

KONG-26

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EXAMINER

WINSTON, RANDALL O

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/717,158	<b>Applicant(s)</b> CHEUNG, LING YUK	
	<b>Examiner</b> Randall Winston	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>0405 and 0305</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submissions filed on 03/14/2005 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a yeast composition and method for its preparation and administration comprising EMF exposure of the one strain of *Saccharomyces cerevisia* Hansen AS2.502 to treat male sexual disorder such as impotence in a mammal, the specification does not enable any person in the art in preparing a yeast composition and method for its preparation and administration comprising EMF exposure of all the yeast species selected from the group consisting of claim 5 to treat male sexual disorder such as impotence in a mammal.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a yeast composition and method for its preparation and administration comprising EMF exposure of yeast species selected from the group consisting of claim 5 to treat male sexual disorder such as impotence in a mammal. Applicant has reasonably demonstrated on page 22, example 2 and paragraph 0048 of the specification, a yeast composition and method for its preparation and administration comprising EMF exposure of the one strain of *Saccharomyces cerevisia* Hansen AS2.502 to treat male sexual disorder such as impotence in a mammal. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a yeast composition and method for its preparation and administration comprising EMF exposure of all the yeast species selected from the group consisting of claim 5 to treat male sexual disorder such as impotence in a mammal.

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a yeast composition and method for its preparation and administration comprising a yeast composition and method for its preparation and

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administration comprising EMF exposure of all the yeast species selected from the group consisting of claim 5 to treat male sexual disorder such as impotence in a mammal. For example, Cutler teaches (US 7041677 see, e.g. column 2 lines 38-43) that Papaverine is widely used to treat impotence. Thus, the art is silent regarding the efficacy of applicant's yeast composition and method for its preparation and administration comprising EMF exposure of all the yeast species selected from the group consisting of claim 5 to treat male sexual disorder such as impotence in a mammal. Therefore, applicant's claimed yeast composition and/or methods is unpredictable in the art.

Furthermore, applicant's specification has reasonably demonstrated on page 22, example 2 and paragraph 0048 of the specification, a yeast composition and method for its preparation and administration comprising EMF exposure of the one strain of *Saccharomyces cerevisia* Hansen AS2.502 to treat male sexual disorder such as impotence in a mammal. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a yeast composition and method for its preparation and administration comprising EMF exposure of all the yeast species selected from the group consisting of claim 5 to treat male sexual disorder such as impotence in a mammal. Therefore, it would require undue experimentation by one of skill in the art to practice the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the recitation "yeast cells are characterized by their ability to treat to treat male sexual disorder in a mammal". The characterization of yeast cell by their "ability" to have an effect on a subject, the nature of which is undisclosed, does not constitute a proper characterization. There is no indication of how the yeast gets to the subject to "treat male sexual disorder" for example, to demonstrate this "ability".

In addition, the nature of the yeast composition, dosage and mammal treated are undisclosed.

Claims 1-13 are further indefinite in the nature of the "yeast cells" of the plurality used are being compared in the last phrase of the claims. For a valid comparison, they should be cells of the same strain.

The characterization of "*Saccharomyces sp.*" in claim 5 as a "species" of *Saccharomyces* is improper.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 7-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-7 of US Patent No. 6,759,055; claims 1-4 and 7-8 of US Patent No. 6,756,050; claims 1-4 and 6-7 of US Patent No. 6,753,008; claims 1-4 and 6-78 of US Patent No. 6,709,849; claims 1-4 and 6-7 of US Patent No. 6,660,508; claims 1-4 and 6-7 of US Patent No. 6,649,383; claims 1-3 and 5-10 of US Patent No. 6,440,713.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the plurality of yeasts, including *S. cerevisiae*, claimed as a product by process are produced in a substantially similar process of making by treating with electromagnetic energy in the various patents and in the instant application.

Claims 1-5 and 7-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,5,7-11 of copending Application No. 10/186,505; claims 1-4 and 6-8 of copending Application No. 10/184,749; claims 1-4 and 6-12 of copending Application No. 10/185,276; claims 1-4 and 6-8 of copending Application No. 10/187,114.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the plurality of yeasts, including *S. cerevisiae*, claimed as a

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product by process are produced in a substantially similar process of making by treating with electromagnetic energy in the various patents and in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-4 of copending Application No. 10/175,014; claims 1 and 3-4 of copending Application No. 10/175,015; claims 1 and 3-4 of copending Application No. 10/175,016; claims 1 and 3-4 of copending Application No. 10/175,049; claims 1 and 3-4 of copending Application No. 10/175,050; claims 1 and 3-4 of copending Application No. 10/175,053; claims 1 and 3-4 of copending Application No. 10/175,054; and claims 1 and 3-4 of copending Application No. 10/175,058.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the plurality of yeasts, including *S. cerevisiae*, claimed as a product by process are produced in a substantially similar process of making by treating with electromagnetic energy in the various patents and in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.



Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable claims 1-4 of copending Application No. 10/460,246; claims 1-4 of copending Application No. 10/460,247; claims 1-4 of copending Application No. 10/460,271; claims 1-4 of copending Application No. 10/460,323; claims 1-4 of copending Application No. 10/460,324; claims 1-4 of copending Application No. 10/460,325; claims 1-4 of copending Application No. 10/460,326; claims 1-4 of copending Application No. 10/460,327; claims 1-4 of copending Application No. 10/460,328; claims 1-4 of copending Application No. 10/460,336; claims 1-4 of copending Application No. 10/460,337; claims 1-4 of copending Application No. 10/460,338; claims 1-4 of copending Application No. 10/460,341; claims 1-4 of copending Application No. 10/460,437; claims 1-4 of copending Application No. 10/460,438; claims 1-4 of copending Application No. 10/460,530; claims 1-4 of copending Application No. 10/460,832; claims 1-4 of copending Application No. 10/460,833; claims 1-4 of copending Application No. 10/717,008; claims 1-4 of copending Application No. 10/717,008; claims 1-4 of copending Application No. 10/717,008; claims 1-4 of copending Application No. 10/717,008; claims 1-4 of copending Application No. 10/717,132; claims 1-4 of copending Application No. 10/717,133; claims 1-4 of copending Application No. 10/717,134; claims 1-4 of copending Application No. 10/717,135; claims 1-4 of copending Application No. 10/717,136; claims 1-4 of copending Application No. 10/717,143; claims 1-4 of copending Application No. 10/717,137; claims 1-4 of

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copending Application No. 10/717,272; claims 1-4 of copending Application No. 10/717,275.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the plurality of yeasts, including *S. cerevisiae*, claimed as a product by process are produced in a substantially similar process of making by treating with electromagnetic energy in the various patents and in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Dutta et al. (J. of Microwave Power (1979), vol. 14, No. 3, pages 275-280).

The claims are directed to a composition comprising yeast cells treated with electromagnetic energy at various frequencies and field strengths for an undisclosed time period.

Dutta et al. teach a biological composition comprising yeast of the species *Saccharomyces cerevisia* which has been prepared by substantially the same process as the instant composition. See, e.g. page 276.

The recited abilities are an inherent property of the yeast preparation.

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by the admitted prior art as evidenced by the website titled "*Saccharomyces cerevisia* Meyen ex Hansen Chinese Strain name" (<http://www.im.ac.cn/database/CCCCM/YEAST/y122.htm>), April 24, 1996.

The claims are directed to a composition comprising yeast cells treated with electromagnetic energy at various frequencies and field strengths for an undisclosed time period.

As admitted by applicants, yeast cells as the instantly claimed are old and well known in the art (see, e.g. specification pages 2-11). Since the claimed invention is not directed to permanently altered yeasts, the claimed invention is anticipated by the yeasts of the prior art. While the electric field applied increase metabolic activity, it does not produce a permanently altered yeast product.

The recited abilities are an inherent property of the yeast preparation.

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Claims 1-4 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen (Derwent ACC-No; 2002-011816 or CN 1309175A, see abstract).

The claims are directed to a composition comprising yeast cells treated with electromagnetic energy at various frequencies and field strengths for an undisclosed time period.

Chen teaches a health care yeast composition in liquid form which has various favorable biological properties.

Since the claimed invention is not directed to permanently altered yeasts, the claimed invention is anticipated by the yeasts of the prior art. While the electric field applied increase metabolic activity, it does not produce a permanently altered yeast product. (see, e.g. abstract)

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima

facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Please note that the intended use of the above claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Claims 1-4 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans (Derwent ACC-No; 1975-41471W or GB 1397873, see abstract).

The claims are directed to a composition comprising yeast cells treated with electromagnetic energy at various frequencies and field strengths for an undisclosed time period.

Evans teaches a health care yeast composition which is in powdered form that is reconstituted to drink form which has favorable biological properties. (see, e.g. abstract)

Since the claimed invention is not directed to permanently altered yeasts, the claimed invention is anticipated by the yeasts of the prior art. While the electric field applied increase metabolic activity, it does not produce a permanently altered yeast product.

The recited abilities are an inherent property of the yeast preparation.

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Please note that the intended use of the above claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by the admitted prior art as evidenced by the website titled "*Saccharomyces cerevisia* Meyen ex Hansen Chinese Strain name" (<http://www.im.ac.cn/database/CCCCM/YEAST/y122.htm>), April 24, 1996 in view of Dutta et al., Evans and Chen.

As admitted by applicants, yeast compositions as the instantly claimed are old and well known in the art (see, e.g. specification pages 2-11).

The reference differs from the claimed invention in the preparation of the yeast by subjecting to electromagnetic energy. However, Dutta et al. teach yeast products produced in this manner at substantially similar conditions. See, e.g. page 276.

The references also differ from the claimed invention in providing the composition in the form of tablet, powder or health drink. However, Evans teaches a health care yeast composition which is in powdered form that is reconstituted to drink form which has favorable biological properties. (see, e.g. abstract)

In addition, Chen teaches a health care yeast composition in liquid form which has various favorable biological properties.

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of the recited website by activating the yeast by treating with electromagnetic energy as taught by Dutta et al. and providing it in powder or drink form as suggested by the teachings of Evans and Chen for the expected benefit of providing a stable composition that can be used to provide essential minerals and vitamins and thus promote the biological activities of

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enzymes in the body and increase well being as to treat conditions such as sexual disorders in an individual.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CHRISTOPHER R. TATE  
PRIMARY EXAMINER